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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,461	03/02/2001	Esteban Cvitkovich	4512/80212	9636

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EXAMINER	
SPIVACK, PHYLLIS G	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/787,461	CVITKOVICH ET AL.	
	Examiner	Art Unit	
	Phyllis G. Spivack	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *082504*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' Amendment filed August 25, 2004 and Response filed December 7, 2004 are acknowledged. Claims 1-11 are canceled. New claims 12-22 are presented and represent all of the claims under consideration.

An Information Disclosure Statement filed August 25, 2004 is further acknowledged and has been reviewed.

The disclosure is objected to for the following informality: The heading A Brief Description of the Figure is required on page 16.

Appropriate correction is required.

Applicants' argument in response to the assertion that the claims presented on August 25, 2004 are drawn to an invention distinct from and independent of the invention previously claimed is persuasive because of overlapping subject matter between the original claim presentation of that of August 25, 2004. Accordingly, the Notice of Non-responsiveness is withdrawn. Claims 12-22 are examined in their entirety.

An amendment to the Abstract is noted.

The rejections of record of claim 1 under 35 U.S.C. 112, second paragraph, and 35 U.S.C. 101 are moot following the cancellation of the claims.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/492320. Although the conflicting claims are not identical, they are not patentably distinct from each other because of overlapping subject matter with respect to dosing regimens.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 12-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to the treatment of any cancer comprising administration of Et-743 at intervals of about 1-6 weeks with an infusion time of about 2 to about 24 hours. The specification provides support for the treatment of melanoma, leiomyosarcoma, colon stromal sarcoma, gastric stromal sarcoma, osteosarcoma, liposarcoma, breast cancer, ovarian cancer, mesothelioma, ocular melanoma comprising administering ET-743 at distinct dosing regimens for each.

Attention is directed to In re Wands, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

1) the quantity of experimentation necessary

2) the amount of direction or guidance provided

3) the presence or absence of working examples

4) the nature of the invention

5) the state of the art

6) the relative skill of those in the art

7) the predictability of the art and

8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to treatment of any cancer comprising administration of Et-743 at intervals and infusion time that are clearly set forth for each neoplastic disease.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the field of oncology.

Each particular neoplastic disease has its own specific characteristics and etiology. The unpredictability observed with single agent therapy is compounded when a combination of agents is employed. The broad recitation "treatment of a human patient for cancer" is inclusive of many pathologies that presently have no established successful therapies.

It is clear the art to which the present invention relates is highly unpredictable and unreliable with respect to conclusions drawn from laboratory data extrapolated to clinical efficacy.

The breadth of the claims

The claims are very broad in terms of dosing options and types of cancers.

The amount of direction or guidance provided and the presence or absence of working examples

The working examples are directed to the various tumor types wherein each is associated with specific dosing regimens in order to achieve a clinical response. There are no working examples where combination therapy with ET-743 is demonstrated.

The quantity of experimentation necessary

Applicants have provided guidance as to which particular dosing regimen is favorably associated with each tumor type. The skilled artisan would not expect a therapeutic dosing regimen for ocular melanoma to be efficacious in the treatment of leiomyosarcoma. Only through experimentation are optimal regimens determined. Claim 1 encompasses treatment for any cancer within a broad dosing schedule to be repeated at intervals of 1-6 weeks. The instant specification is enabling for some

cancer therapy, but it does not provide enablement for any cancer or a dosing regimen for any cancer. Therefore, absent reasonable *a priori* expectations of success, one skilled in the oncology art would have to test extensively many dosing regimens to discover which provides a positive therapeutic effect for a particular cancer. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

In the last Office Action claims 1-3, 5 and 9 were rejected under 35 U.S.C. 102(b) as being anticipated by Drugs Fut., claims 1-9 were rejected under 35 U.S.C. 102 (a) as being anticipated by Izbicka et al., Annals of Oncology, and claims 1-11 were rejected under 35 U.S.C. 103 as being unpatentable over Izbicka et al., Annals of Oncology. These rejections of record are withdrawn because the references do not teach or suggest administration of Et-743 at intervals of about 1-6 weeks with an infusion time of about 2 to about 24 hours.

Goodman & Gilman's The Pharmacological Basis of Therapeutics, is cited to show further the state of the art. Combination therapy is desirable according to Goodman & Gilman. See the third paragraph on page 1230. Further, optimal dosing requires the consideration of specific phases of the cell cycle. The discussion under Achieving Therapeutic Balance and Efficacy on page 1232 provides motivation to one skilled in the art to seek optimal dosing regimens for specific cancers and the stage at

which the disease presents. Dosing in multiple cycles is a conventional approach to therapy to enable recovery of those normal tissues adversely affected by drug therapy.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached Monday to Friday from 10:30 AM to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful are unsuccessful, the Examiner's supervisor, Chris Low, can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phyllis Spivack

Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER